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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,751	04/18/2001	Allan Green	45-00	8897

23713 7590 11/10/2003

GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

12

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,751

Applicant(s)

GREEN ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-108 is/are pending in the application.
- 4a) Of the above claim(s) 66,78 and 86-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62-65,67-77,79-85 and 101-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed January 21, 2003 has been entered.

Claims 1-61 have been cancelled.

Claims 62-108 are newly submitted.

Election/Restrictions

1. Applicants' election with traverse of Group VI, SEQ ID NO: 3 and 4, in Paper No. 7 and 11 is acknowledged. Applicants assert that synonymous coding sequences should be examined together. The Examiner will examine SEQ ID NO: 3 and sequences coding for SEQ ID NO: 4. Applicants also argue in the response of January 21, 2003 that groups relating to delta 12 fatty acid desaturase and groups relating to interrupted inverted repeats should be rejoined. The Examiner has rejoined these groups and will examine the newly filed claims to the extent that they read on these groups and to SEQ ID NO: 3 or 4. Applicants further request that Groups X, XI and XIII be rejoined as they are drawn to the use of delta-9 and delta-12 desaturase genes together and would be a subset of the use of delta-12 desaturase genes. The Examiner maintains that these claims are drawn to separate inventions that are patentably distinct given that additional searching is required and the methods require different components and result in different products. It would be an undue burden to search and examine the additional claims. Given that the originally filed claims have been cancelled, the Examiner has determined that the pending claims 62-65, 67-77, 79-85 and 101-108 are drawn to the elected invention to the extent that the claims are drawn to SEQ ID NO: 3 and 4. Amendment of the claims to delete the other sequences is required.

Claims 66 and 78 are withdrawn as drawn to SEQ ID NO: 7; and claims 86-100 are withdrawn as drawn to methods requiring delta-9 desaturase genes.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 62-65, 67-77, 79-85 and 101-108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of decreasing expression of a delta-12 fatty acid desaturase by transforming a cotton plant with a construct comprising either a full length delta-12 fatty acid desaturase gene in antisense or with a construct comprising inverted repeats of a delta-12 fatty acid desaturase gene that are 850 bp and optionally with a 92 bp intervening sequence, as well as the transgenic cotton plants and seeds produced by said method, does not reasonably provide enablement for the same method wherein the construct merely comprises a 20 nucleotide fragment of a delta-12 desaturase gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only discloses a method of decreasing expression of a delta-12 fatty acid desaturase by transforming a cotton plant with a construct comprising either a full length delta-12 fatty acid desaturase gene in antisense or with a construct comprising inverted repeats

of a delta-12 fatty acid desaturase gene that are 850 bp and optionally with a 92 bp intervening sequence, as well as the transgenic cotton plants and seeds produced by said method (see page 92). The specification does not teach use of constructs having as little as 20 nucleotides for decreasing expression of the delta-12 desaturase gene, in either sense or antisense orientation, or as inverted repeats. However, Stam et al (submitted by applicants with the response filed January 21, 2003) teach that the mechanism of antisense transgenes to degrade complementary RNAs is poorly understood, and that small antisense molecules have difficulty accessing complementary RNAs (see page 27).

Therefore, given the unpredictability of using small antisense molecules to decrease expression of endogenous genes, as taught by Stam et al; and given the lack of working examples of sequences other than the full length antisense sequence or 850 bp inverted repeat sequences; and given the absence of guidance with regard to how one would choose from the multitude of other sequence fragments and inverted repeats that optionally have an intervening sequence; and given the breadth of the claims, which encompass a vast number of possible sequences and lengths of sequences; it would require undue experimentation by one skilled in the art to make and/or use the invention as broadly claimed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

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person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 62, 63, 67-75, 79-85, 101, 102 and 106-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lightner et al (U.S. Patent 6,372,965).

The claims are drawn to a method of decreasing expression of a delta-12 fatty acid desaturase by transforming a cotton plant with a construct comprising either a full length delta-12 fatty acid desaturase gene in antisense or with a construct comprising inverted repeats of a delta-12 fatty acid desaturase gene that are at least 20 nucleotides in length, and cotton plants and seeds produced by said method.

Lightner et al teach transformation of plants with at least portions of a delta-12 desaturase gene in sense or antisense orientation and operably linked to a seed specific promoter to modify the endogenous oil content of a plant (columns 27-28). Lightner et al teach SEQ ID NO: 11 (nucleotides 1175-1203) which has more than 20 nucleotides that are identical to SEQ ID NO: 3 at nucleotides 1057-1085. Lightner et al also teach the desirability of transforming cotton (column 30).

Lightner does not specifically teach using the soybean lectin promoter or exemplify a transformed cotton plant.

Given the recognition of those of ordinary skill in the art of the value of transforming a plant with with at least portions of a delta-12 desaturase gene in sense or antisense orientation and operably linked to a seed specific promoter to modify the endogenous oil content of a plant, as taught by Lightner et al, and given the teaching of Lightner et al of the desirability of transforming a cotton plant to modify the endogenous oil in the seed, it would have been obvious to use the teachings of Lightner to transform a cotton plant to produce a cotton plant with modified endogenous oil content, and it would have been obvious to substitute other seed preferred promoters to have the same effect. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

7. Claims 64, 65, 76, 77, 78, 103, 104 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lightner, as stated above, and further in view of Bedbrook (U.S. Patent 5,952,546).

Lightner et al teach transformation of plants with at least portions of a delta-12 desaturase gene in sense or antisense orientation and operably linked to a seed specific promoter to modify the endogenous oil content of a plant (columns 27-28). Lightner et al teach SEQ ID NO: 11 (nucleotides 1175-1203) which has more than 20 nucleotides that are identical to SEQ ID NO: 3 at nucleotides 1057-1085. Lightner et al also teach the desirability of transforming cotton (column 30).

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Lightner does not teach use of inverted repeats.

Bedbrook et al teach use of inverted repeats in an antisense construct to decrease expression of an endogenous gene (see claim 1, for example).

Given the recognition of those of ordinary skill in the art of the value of transforming a plant with with at least portions of a delta-12 desaturase gene in sense or antisense orientation and operably linked to a seed specific promoter to modify the endogenous oil content of a plant, as taught by Lightner et al, and given the teaching of Lightner et al of the desirability of transforming a cotton plant to modify the endogenous oil in the seed, it would have been obvious to use the teachings of Lightner to transform a cotton plant to produce a cotton plant with modified endogenous oil content, and it would have been obvious to substitute a construct having inverted repeats, given the teachings of Bedbrook. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

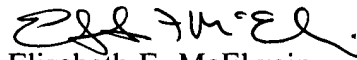
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is 703-308-1794. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Elizabeth F. McElwain

Primary Examiner

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EFM